Special 510(k): Device Modification
CXC Support Catheter
Cook Incorporated
29 September 2009

DEC - 8 2009

510(k) SUMMARY

Submitted By: Molly Busenbark
Cook Incorporated
750 Daniels Way
Bloomington, IN 47404

Device:

Trade Name: CrossCath Support Catheter
Proposed Classification: Catheter, Continuous Flush
KRA (21 CFR §870.1210)

Indications for Use:

The CrossCath Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.

Predicate Device:

The CrossCath Support Catheter is similar in terms of intended use, principles of operation, materials of construction, and technological characteristics to the predicate device reviewed as a device for use in small vessel or superselective anatomy for diagnostic and interventional procedures.

Device Description:

CrossCath Support Catheters with hydrophilic coating are single lumen intravascular catheters, designed to support a wire guide during access of vasculature, allow for exchange of wire guides, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

CrossCath Support Catheters are available in nine different configurations. All models have three radiopaque markers spaced equally along the distal shaft to aid in estimating lengths within the vascular system. The distal radiopaque maker is positioned approximately 3 mm from the catheter tip. Each model has a smaller distal portion for passing through smaller vasculature and a larger proximal portion for additional support. The models with 0.014" and 0.018" end holes have hydrophilic coating at the distal 40 cm portion. The models with 0.035" end holes have hydrophilic coating at the distal 60 cm portion.

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Substantial Equivalence:

Cook Incorporated currently markets the predicate CXI Support Catheter, cleared for marketing on November 9, 2007 (D.C. #K072724). The similar indications for use, principals of operation, and technological characteristics of the CrossCath Support Catheter as compared to the predicate device support a determination of substantial equivalency.

Test Data:

The proposed CrossCath Support Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters.

- Tensile Testing
- Leakage Testing
- Burst Pressure Testing
- Flow Rate Testing
- Accelerated Aged Testing
- Biocompatibility Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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Cook Incorporated
c/o Ms. Molly Busenbark
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47402-0489

Re: K093052
Trade/Device Name: CrossCath Support Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: November 3, 2009
Received: November 4, 2009

Dear Ms. Busenbark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093052

Device Name: CrossCath Support Catheter

Indications for Use for the CrossCath Support Catheter:

The CrossCath Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.

Prescription Use XX (Part 21 CFR 801 Subpart D) OR Over-the-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093052